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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,101	02/04/2004	Jacques Seguin	CVALVE.006CP1	6184
20995 7590 11/01/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER SCHILLINGER, ANN M	
			ART UNIT 3774	PAPER NUMBER
			NOTIFICATION DATE 11/01/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

# Office Action Summary

Application No.

10/772,101

Applicant(s)

SEGUIN ET AL.

Examiner

Ann Schillinger

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 111-149 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 111-149 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment A</u>                       |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claim 137 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 3-4, it is unclear if the leaflet claimed belongs to the cardiac valve or the cardiac valve support.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-116, 118-124, 127-131, 133-146, 148, and 149 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (U.S. Pub. No. 2002/0151970). Garrison et al. discloses the following regarding claim 111: a prosthetic cardiac valve (6) with a base (40, 26, 28, 30, 31, 34), a plurality of commissure points (see Figure 10, 32), and a plurality of resilient leaflets (paragraph 0061) (Figure 10). Garrison et al. also discloses a collapsible prosthetic cardiac valve support (8; paragraph 0057), with a first and a second portion (Attachment A), and a first and a second section. The first section expands to a diameter less than first portion (see Figure 8). Please note that functional language is used throughout the claims, and in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of

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sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.G. 279.

Garrison et al. discloses limitations of claims 112, 113, 119, 120, and 149 the radial restraint comprising a wire (see Figure 7; paragraph 0058, lines 10-13).

Garrison et al. discloses the limitations of claims 114 and 115 as shown in Figures 9 and 27-33.

Garrison et al. discloses the limitations of claim 116 in paragraph 0069.

Garrison et al. discloses the anchor of claims 118 and 148 in paragraph 0080.

Garrison et al. discloses the following regarding claim 121: the prosthetic cardiac valve assembly of Claim 15, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force (see Figure 7, where the wire shown in capable of decreasing the radial expansion force). With this claim language, Applicant is not disclosing that the wire's thickness varies within the same length of the wire.

Garrison et al. discloses the limitations of claim 122 in Figure 7 and paragraph 0058.

Garrison et al. discloses the limitations of claim 123 and 139 in paragraph 0080.

Garrison et al. discloses the limitations of claim 124 in paragraph 0069.

Garrison et al. discloses the limitations of claim 127, 133, 138, and 146 in paragraph 0080.

Garrison et al. discloses the limitations of claim 128, 136, 140, and 144 in paragraph 0012.

Garrison et al. discloses the limitations of claim 129, 134, and 141 in paragraph 0069.

For claims 130, 131, 142 Garrison et al. discloses a ring stent (111), see Figure 37.

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Garrison et al. discloses the limitations of claim 135 and 143 in paragraphs 0008 and 0009.

Garrison et al. discloses the following regarding claim 137: a prosthetic cardiac valve assembly (6, 8) with an axial cardiac valve support portion (8). The support portion has a second section, and at least one radial restraint (see Figure 7; paragraph 0058, lines 10-13) at a first section (see Attachment A). Please also see paragraphs 0058-0080.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 117 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. et al. in view of Schwartz et al. (US Pub. No. 2002/0099439). Garrison et al. discloses the claimed invention except for a drug-eluting component that is included with the valve. Schwartz et al. teaches including such a compound with the valve to prevent cell overgrowth or extracellular matrix production in the same field of endeavor (paragraphs 0014, 0023, 0083). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include these drug-eluting compounds with the valve to prevent cell overgrowth or extracellular matrix production.

Claim 125 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Kocur (US Patent No. 6,350,277). Garrison et al. does not disclose the use of a shape memory material. However, Kocur teaches the use of nitinol in a stent (col. 6, lines 36-39) that

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will assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory material such as nitinol to assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve.

Claim 126 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Shaolian et al. (US Patent No. 6,299,637). Garrison et al. does not disclose the use of a cuff constraint component. Shaolian et al. teaches the use of a cuff in the same field of endeavor in elements 50, 52, 54; col. 6, lines 30 through col. 7, lines 5 for the purpose of providing radial support. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use cuff constraint component in order to provide radial support.

Claims 132 and 147 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Kocur (US Patent No. 6,350,277). Garrison et al. discloses the use of a stent with the valve system, but does not disclose all of the specific features of the stent as described by the applicant. Kocur discloses the valve assembly further composing a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26). And Kocur discloses the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to these specifications to allow the stent to work more efficiently with the prosthetic valve system.

*Response to Arguments*

In view of the new claims submitted by the Applicant, the Applicant's arguments with respect to the previous claims have been considered but are moot in view of the new ground(s) of rejection.


*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger  
October 28, 2007

  
CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700

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Attachment A

